TBS/QMD/PPR/G/02

TANZANIA BUREAU OF STANDARDS

CRITERIA FOR GMP INSPECTION OF HIGH RISK FOOD MANUFACTURING FACILITIES

SEPTEMBER, 2023

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ACKNOWLEDGEMENT

These Criteria have been developed by Team members based on their experience and knowledge in order to enhance food manufacturers to comply with Good Manufacturing Practices (GMP) requirements.

I would like to express my sincere gratitude to all members of the Directorate of Quality Management who contributed to the drafting and writing of these criteria.

I would also like to sincerely thank all persons and groups that reviewed and made constructive comments and inputs to the Criteria. I particularly acknowledge TBS Management Team for providing valuable comments to the Criteria.

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Ag. DIRECTOR OF QUALITY MANAGEMENT

FOREWORD

Quality is a summation of the intangible factors necessary and sufficient to assure performance of desired functions. It cannot be tested into a product only, but must be built into it by reliable workers in every phase of processing and production. The excellence of a company's products reflects the integrity, competence, and pride of all those involved in the design, production, and marketing of the products.

One of the most well known sets of requirements that have a major impact on the food industries is Good Manufacturing Practices (GMP). These criteria address the requirements for premises, equipment, personnel, quality and process controls, documentation, storage, validations, and manufacturing processes including packaging and labeling.

These should be considered as general criteria and should be adopted to meet individual needs, making sure that the established standards of quality for food are still achieved.

These GMP Inspection criteria shall be used to justify GMP status as a prerequisite prior to registration of high-risk food products into Tanzania. It is my hope that it will be useful during assessment of food manufacturing facility on compliance to GMP requirements.

Dr. Ngenya,Y.A.
DIRECTOR GENERAL

DEFINITIONS

The definitions are given for the purpose of these criteria.

Analytical method — Means detailed description of the procedures to be followed in performing tests for conformity with Specification

Bulk Product — Means any product which has completed all processing stages up to, but not including, packaging (not applicable to those products where processing takes place inside the container and the latter is itself therefore part of the processing)

Competent authority — Means any person or organization that has the legally delegated or invested authority, capacity, or power to perform a food control regulatory functions.

Contract manufacture — Means manufacture or partial manufacture ordered by one person or organization (the Contract Giver) and carried out by a separate person or organisation (the Contract Acceptor).

Documentation — Means written production procedures, instructions and records, quality control procedures, and recorded test results involved in the manufacture of a product.

Finished Product — Means a product which has undergone all stages of manufacture and packaging.

Food Allergen — Means a food substance which, in some sensitive individuals, causes an immune response causing bodily

reactions resulting in the release of histamine and other substances into the tissues from the body's mast cells in the eyes, skin, respiratory system and intestinal system.

Genetically Modification Organism — Means an organism whose genetic characteristics have been altered by the insertion of a modified gene or a gene from another organism using the techniques of genetic engineering

Good Manufacturing Practice — Means a combination of manufacturing and quality control procedures aimed at ensuring that products are consistently manufactured to their specifications.

Hazard — Means a biological, chemical or physical agent in, or condition of, food with a potential to cause an adverse health effect.

Ingredients — Means all materials, including starting materials, processing aids, additives and compounded foods, which are included in the formulation of the product.

In-process Control — Means a system of checks made and actions taken during the course of manufacture to ensure that materials at any stage comply with the specification for that stage, and that the processing and processing environment comply with the conditions stated in the Master Manufacturing Instruction.

Manufacture — Means a complete cycle of production of a food from the acquisition of all materials through all stages of subsequent processing, packaging and storage to the dispatch of the finished product.

Novel Foods Means

a) a substance, including a microorganism, that does not have a history of safe use as a food or ;

b) a food that has been manufactured, prepared, preserved or packaged by a process that has not been previously applied to that food, and causes the food to undergo a major change or ;

c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that the plant, animal or microorganism exhibits characteristics that were not previously observed.

Packaging material Means any container or material used in the packaging of a product. This my include materials in direct contact with the product, printed packs, including labels, carrying statutory and other information, and other packaging materials including outer cartons or delivery cases. These categories are, of course, not necessarily mutually exclusive.

Processing Means the transformation of raw ingredients into food, or of food into other forms.

Quality Assurance Means the total of the organized arrangements made with the objective of ensuring that finished products are of the quality required for their intended use.

Quality Control Means part of GMP that ensures raw materials are not released for use, and that finished product are not released

for sale or supply, until their quality has been deemed satisfactory.

Quality Management — Means a comprehensively designed and correctly implemented system of Quality Assurance (QA) that incorporates Good Manufacturing Practices (GMP) and Quality Control (QC).

Raw Material — Means any material, ingredient, starting material, semi-prepared or intermediate material, packaging material, etc, used by the manufacturer for production of a product.

Risk — Means the probability that a particular adverse consequence results from a hazard within a stated time under stated conditions.

Specification — Means a document giving a description of material, machinery, equipment, process of product in terms of its required properties or performance.

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DOCUMENT NO: TBS/QMD/PPR/G02	TITLE: Criteria for GMP Inspection of High Risk Food Manufacturing Facilities	Revision: 00	Page 1 of 23
DOCUMENT TYPE: Guideline	PREPARED BY: Director of Quality Management (DQM) Sign:	APPROVED BY: Director General Sign:	EFFECTIVE DATE: 1st September, 2023

INTRODUCTION

These GMP Inspection Criteria stipulate the minimum requirements for Good Manufacturing Practice in a food manufacturing facility. These Criteria are not static and therefore improvements can be made as deemed necessary.

The purpose of these Criteria is to outline the responsibilities of food facility managers in relation to the efficient manufacture and control of food products; thereby ensuring that such products are safe, wholesome and of the nature and quality intended. The criteria will also be used as a reference for inspectors while carrying out inspection of overseas High Risk Food manufacturing facilities.

These criteria form the basis for inspection of overseas food manufacturing facility for the purpose of registration of imported food products.

These GMP Inspection Criteria comprises of three chapters. Chapter one highlights the requirements for location and design of the manufacturing plant. Chapter two elaborate the requirements for manufacture, packaging and quality management. Chapter three provides the requirements for personnel hygiene, education and training.

These Criteria have been annexed with inspection checklist in order to systematically guide the inspected during assessment GMP.

Adherence to these criteria by food manufacturers will contribute substantially to the manufacture of consistently uniform batches of good quality and safe food products.

CHAPTER ONE

REQUIREMENTS FOR LOCATION AND DESIGN OF THE MANUFACTURING PREMISES AND EQUIPMENT

1.0 PREMISES AND EQUIPMENT

1.1 Plant and grounds.

a) Plant layout and production flow chart should be available.
b) Production should be authorized by the National Food Regulatory Body.
c) Plant should be kept in condition that protects against contamination of food.

1.2 Plant construction and design

Plant buildings and structures should:

a) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
b) Permit the taking of proper precautions to protect food in outdoor bulk containers by any effective means such as using protective coverings.
c) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and in good state of repair;
d) Be constructed in such a manner that aisles or working spaces are provided between equipment and walls. They should be adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces.

e) Provide adequate lighting in all areas (such as hand-washing, dressing, locker rooms and toilet rooms) of the plant.
f) Provide well-protected safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation.
g) Provide adequate ventilation using control equipment such as fans and other air-blowing equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food;
h) Provide (where necessary) adequate screening or other protection against pests.

1.3 Sanitary operations

1.3.1 General maintenance

Buildings, fixtures, and other physical facilities of the plant should be maintained in a sanitary condition and should be kept in repair sufficient to prevent food from being contaminated.

1.4 Substance used in cleaning and sanitizing

The requirements for substance used in cleaning which aim at preventing contamination include the following:

a) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures be free from undesirable microorganisms and should be safe and adequate under the conditions of use.
b) Cleaning compounds, sanitizing agents and pesticide chemicals be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

1.5 Pest control

a) Effective measures should be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests.
b) Use where applicable, insecticides or rodenticides in a manner that will not contaminate food, food-contact surfaces, and food-packaging materials.

1.6 Sanitation of food-contact surfaces

a) All food-contact surfaces, including utensils and equipment should be cleaned as frequently as necessary to prevent from contamination of food.
b) Food-contact surfaces used for manufacturing or holding low-moisture food should be in a dry, sanitary condition at the time of use.
c) Single-service articles (such paper cups and towels) should be stored in appropriate containers, handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

1.8 Water supply.

a) The water supply should be sufficient and safe for the operations intended and should be derived from an adequate source.
b) Running water at a suitable temperature, and under pressure as needed, should be provided in all areas where required for the manufacturing plant.

1.9 Plumbing

Plumbing should be of adequate size and design and adequately installed and maintained to: -

a) Carry sufficient quantities of water to required locations throughout the plant.

b) Properly convey sewage and liquid disposable waste from the plant.
c) Prevent back flow of waste water and sewage.
d) Provide adequate floor drainage in all areas where floors are subject to flooding type

1.10 Sewage and waste disposal

a) Waste should be so conveyed, stored, and disposed of as to minimize the development of odor and potential for the waste becoming an attractant and harborage or breeding place for pests.
b) Refuse receptacles should be constructed and maintained in a manner that protects against contamination of food.

1.11 Toilet facilities

a) Plant should be provided with adequate toilet facilities.
b) Toilet facilities should be provided with self-closing doors.
c) The toilet facilities should be kept in a good state of repair and maintained sanitary condition.
d) Toilet doors should not open into areas where food is exposed to avoid contamination.

1.12 Hand-washing facilities

a) Plant should be provided with adequate and convenient hand-washing facilities.
b) Plant should be provided with readily understandable signs directing employees to clean and sanitize their hands before handling unprotected food.
c) Devices or fixtures, such as water control valves, should be designed and constructed to protect against recontamination of clean and sanitized hands.

1.13 Equipment and utensils

a) Plant equipment and utensils should be so designed to be cleanable.
b) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture non-human food-grade animal feed.
c) Instruments used for measuring, regulating, or recording conditions (temperatures, pH, acidity, water activity) should be accurate and sufficient in number.
d) Food contact surfaces should be corrosion-resistant.
e) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, should be of a design and construction that enables them to be maintained in an appropriate sanitary condition.
f) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment should be treated in such a way that food is not contaminated with unlawful indirect food additives

1.14 Storage

a) Adequate facilities for storage of food, ingredients and non-food chemicals should be provided
b) Storage area should be designed to prevent pests, contamination and degradation of ingredients, finished products or packing material from dust, debris and any other environmental factors.
c) Product stocking system should allow proper product rotation in place.
d) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms should be fitted with temperature measuring and/or recording device to show the temperature accurately within the compartment/freezer.

CHAPTER TWO

2.0 REQUIREMENTS FOR MANUFACTURE, PACKAGING AND QUALITY MANAGEMENT

2.1 Processes and controls

a) All production processes should be conducted in accordance with Good Hygienic Practice (GHP).
b) Appropriate quality control personnel should be employed to ensure production of safe food.
c) Chemical, microbial, or physical quality testing procedures should be used to identify sanitation failures or possible food contamination.

2.2 Raw materials and other ingredients.

a) Raw materials and other ingredients should be cleaned as necessary to remove soils and other contaminants.
b) Acceptance criteria of raw materials in terms of microbial, chemical as well as physical quality and safety specifications should be in place.

2.3 Manufacturing operations.

a) All food manufacturing operations including filling, packaging and storage should be conducted under safety and quality control conditions.
b) Finished foods should be protected from contamination by raw materials, other ingredients or refuse.

2.4 Good control laboratory practices

a) Laboratory facilities should be capable of conducting analysis of the appropriate parameters.
b) Laboratory staffs should be properly trained and well managed.

c) Quality control activities should be done in accordance to the set National or international standards.

d) Physico-chemical, biological and microbiological laboratories should be separated from each other.

e) Specifications approved by Quality Control and including analytical parameters should be established for all Raw Materials, Bulk, Intermediate and Finished Products.

f) The persons responsible for laboratory management should ensure that suitable test-methods, validated in the context of available facilities and equipment, are adopted or developed.

2.5 Laboratory equipment and instruments

a) Equipment and instruments should be serviced and calibrated at suitable specified intervals by an assigned competent person, persons, or organization.

b) Written operation instructions should be readily available for each instrument.

c) Analytical methods include a control test to verify that the equipment is functioning satisfactorily should be provided.

2.6 Laboratory reagents

Reagents made up in the laboratory should be prepared following the defined procedures below:

a) Reagents made up in the laboratory should be prepared by persons competent to do so, following laid down procedures.
b) Labeling of reagents indicate the concentration, standardization factor, shelf life, and storage conditions.
c) Both positive and negative controls applied to verify the suitability of microbiological culture media.

2.7 Sampling requirements for laboratory analysis

a) Written procedures should be developed for sampling and should specify the method and rate of sampling.
b) All samples should be identified according to standard procedures

c) Methods used for testing should be acceptable to any enforcing authority or internationally acceptable.

2.8 Laboratory records

a) Detailed records should be maintained for all tests and analyses performed in the laboratory.
b) Test results and calibration procedures should be recorded in a good manner that will facilitate comparative reviews of those results and the detection of trends.
c) Analytical records taken should contain: -

   i. name of product or material and code reference;
   ii. date of receipt and sampling;

iii. source of product or material (including supplier and country of origin);
iv. date of testing;
v. batch or lot number;
vi. indication of tests performed;
vii. reference to the methods used;
viii. results;
ix. decision regarding release, rejection or other status;
x. Signature or initials of analyst, and signature of person taking the above decision.

2.9 Product recall

a) Product recall should be done after investigation and evaluation of the complaint.
b) The competent authorities of all countries to which a given product has been distributed should be promptly informed of any intention to recall the product
c) The distribution records of the defective product should be readily available
d) The progress of the recall process should be monitored and recorded
e) The disposal of products should be recorded
f) The effectiveness of the arrangements for recalls should be tested and evaluated from time to time.

2.10 Contracted Manufacturing of the food product

In the case of contract manufacturing, the following criteria should be provided: -

2.10.1 **Responsibility of contract acceptor (manufacturer)**

The terms of the should be contract clearly stated in writing and that raw material and products meet the specifications.

2.10.2 **Responsibility of contract giver (importer)**

a) The contractual conditions, which ensure quality standards should be imposed by contract giver.

b) There should be records showing the manufacturing unit has been visited by contract giver quality control manager to verify the suitability for production of safe food.

2.11 Novel Foods and Processes

Novel foods and processes, including genetic modification (GM) should be clearly declared in relation to safety, environment, information and ethics requirements.

2.12 Control of allergens during processing

a) Separate production equipment, if possible, to control Major Serious Allergens (MSAs)

b) Equipment used to manufacture MSAs containing products cleaned before being re-used.

2.13 Control of allergens through product labeling

The presence or potential presence of an MSA should be clearly stated on the label.

2.14 Quality Management System

The food manufacturing facility should have in place a comprehensive quality management system, so designed, documented, implemented, and furnished with personnel, equipment and resources to ensure that

specifications set to achieve the intended product quality standards are consistently met.

2.15 Documentation

a) Documents should comply with relevant stages of manufacturing and marketing authorizations.

b) Documents should have unambiguous contents; the title, nature and purpose.

c) Master formulae and detailed Standard Operating Procedures should be available

d) Documents should be easily retrieved.

2.16 Documents for Instructions and Procedures

The documents for Instructions and procedures include: -

a) Ingredient specification
b) Packaging material specification
c) Master Manufacturing Instructions (including flow sheets and standard recipes)
d) Bulk Products Specification
e) Finished Products Specification
f) Quality Control Procedures and Methods
g) Cleaning Instruction, Housekeeping and Pest Control Schedules

2.17 Documents for Records

The documents for records and reports include: -

a) Quality Control Records
b) Customer Complaint Records
c) Product recall records

d) Food handlers health records
e) Batch Manufacturing Records
f) Records of Process Control records
g) Records of Quality Audit

CHAPTER THREE

3.0 REQUIREMENTS FOR PERSONNEL

Food manufacturing facility should have competent supervisory personnel for assuring compliance by all personnel with the requirements of personal hygiene, health and training.

3.1 Personnel health requirements

a) Employees should be medically examined by authorized medical practitioner at first appointment and after every six months.

b) Any person who appears to have illness should be excluded from any manufacturing operation.

3.2 Personnel hygiene and behavior

a) All persons working in direct contact with food, food-contact surfaces, and food-packaging materials should conform to hygienic practices while on duty.

b) Employees should not wear jewelry's, watches, pins or other items unless secured to prevent contamination.

c) Employees should wear hairnets, masks, headbands, caps, beard covers, or other effective hair restraints where applicable.

3.3 Personnel education and training on food hygiene

a) Food handlers and supervisors should receive appropriate training on proper food handling techniques and good sanitary practices.

b) Personnel responsible for identifying sanitation failures or food contamination should have the required background of education, experience or a combination thereof, to provide a level of competency necessary for production of clean and safe food.

c) Newly recruited personnel besides acquiring basic training on the theory and practical on GMP, should receive training appropriate to the duties assigned to them.

d) Visitors or/and untrained personnel should be given relevant information in advance and protective gears before taken into the production area.